2413 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0703
(202) 225-3661

59 ELM STREET
SECOND FLOOR
NEW HAVEN, CT 06510
(203) 562-3718

DURHAM/MIDDLEFIELD/MIDDLETOWN
(860) 344-1159

WEBSITE: HTTP://DELAURO.HOUSE.GOV

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July 22, 2009

Margaret Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Hamburg:

As required under Section 230 of the Food and Drug Administration Amendments Act (FDAAA) of 2007, the Food and Drug Administration (FDA) submitted a report to Congress on December 5, 2008 entitled, "Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage."

While this report was written under the previous Administration, there are a series of questions and additional concerns related to the report on the current labeling requirements for indoor tanning devices that need to be addressed.

Consumers must be presented with clear information that allows them to easily recognize the risks associated with indoor tanning and to make informed decisions about their safety and health. Key findings of the FDA's consumer testing reveal that participants found an alternative warning statement to be more effective than the label that currently is required. However, the report does not indicate whether or not the FDA will require the new language.

Additionally, the current common practice of placing the label upon the top canopy of the device defeats much of the label's purpose. The canopy often is open when a customer enters a salon, thereby preventing any view of the warning, so it is critical to implement a placement location that cannot be obstructed by the normal function of the tanning device. In addition to changing the language of the label, a thorough review of its placement is vital to effectively communicating the risks associated with the device.

In its report, the FDA also states that the agency will consider amending the performance requirements regulating sunlamp products, which have not been reviewed or updated since 1985. With the significant technological advances in the indoor tanning industry over the past 24 years, it is imperative that the FDA update its sunlamp product performance standards immediately. This also is of paramount importance in light of extensive research advances which have clearly elucidated the medical implications of elective ultraviolet exposure.

Regarding the issue of the current classification of sunlamp products as a Class I medical device, it is my understanding that classification is based on the factors of risk and intended use. However, it is unclear as to why ultraviolet lamps for tanning are considered a Class I medical device, while other ultraviolet lamps (such as those used to photoactivate a drug for the treatment of a dermatologic disorder) are listed as Class II medical devices. As both devices are UV-emitting sunlamps applied to the skin, it is unclear as to why there are differing classifications. If the difference in classification is determined by the device's risk, the association between ultraviolet lamps for tanning and the threat of developing potentially lethal skin cancers (both melanoma and non-melanoma types) is reason to reexamine the medical device's classification.

Risks of exposure to ultraviolet light, whether natural or artificial, is a critical public health issue that has been well documented. The FDA long has recognized that there are serious health concerns associated specifically with indoor tanning, including increasing skin cancer rates. In a recent hearing before the House Agriculture Appropriations Subcommittee, FDA Deputy Commissioner Joshua Sharfstein acknowledged that tanning beds are an FDA-approved device that "can promote skin cancer."

According to the American Academy of Dermatology, skin cancer is the most prevalent form of cancer with over one million Americans developing the disease every year. Furthermore, malignant melanoma is the most deadly of all skin cancers and is associated with exposure to ultra-violet light. Thus, while these cancers are common and deadly, many of them should be avoidable.

In addition, non-melanoma skin cancers, which are even more abundant than melanoma, also can be lethal and are tightly associated with ultraviolet radiation, including indoor tanning. The evidence suggests that sunlamp devices are contributing to this alarming public health trend, and therefore, there should be a heightened responsibility to protect consumers from the risks associated with indoor tanning.

Given these concerns outlined above, please respond to the following questions based on the FDA report:

1. Because FDA's own consumer testing revealed that alternative warning statement were more effective than the label that currently is required, will the agency implement the alternative warning statement? If so, when?
2. Will the FDA engage in a thorough review of the placement of the label? If this review concludes that the label is obstructed in any way, will the agency consider requiring that the placement of the label be moved to a more prominent location? If so, when?
3. Does the agency intend to review and amend the performance requirements regulating sunlamp products as was suggested in their December 2008 report? If so, when?
4. Taking into consideration that the association between ultraviolet lamps for tanning and the threat of developing malignant skin cancers (both melanoma and non-melanoma forms), will the FDA review the classification of sunlamps and consider assigning it to a different category to reflect its real risk? If so, when?

Thank you very much for your attention to this important public health issue, and I look forward to working with you to protect consumers from harmful indoor tanning products.

Sincerely,

Rosa L. DeLauro

ROSA L. DeLAURO
Chairwoman
House Appropriations Subcommittee on Agriculture
Rural Development, Food and Drug Administration,
and Related Agencies